



10-28 03

3763

PATENT

11-6

11-4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Attorney Docket No. 11738.00038)

In the Application of: )  
Hartlaub et al. ) Group Art Unit: 3763  
Serial No. 10/005,789 )  
Examiner: Kathryn L. Thompson  
Filed: November 8, 2001 )  
For: INFUSION SYSTEMS FOR CREATING )  
MICROENVIRONMENTS IN A LIVING )  
BODY )

RECEIVED  
NOV 03 2003  
TECHNOLOGY CENTER R3700

INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, the Applicants wish to make the following references of record in the above-identified application and state that each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. 1.56. Copies of the references cited below are enclosed. The references are also listed on the enclosed and completed PTO Form 1449.

This Information Disclosure Statement is being filed after receipt of a First Office Action. Accordingly, a fee of \$180.00 is required. The Commissioner is authorized to charge our Deposit Account No. 19-0733.

10/31/2003 SSITHIB1 00000102 190733  
01 FC:1806 180.00 DA

## REFERENCES

### U.S. Patents

1. Masters, US. 2003/0007991 A1, published January 9, 2003;
2. Kühl et al., U.S. Patent No. 4,140,122, issued February 20, 1979;
3. Brown et al., U.S. Patent No. 4,952,406, issued August 28, 1990;
4. Aebischer et al., U.S. Patent No. 5,011,472, issued April 30, 1991;
5. Currie et al., U.S. Patent No. 5,366,454, issued November 22, 1994;
6. Seckel, U.S. Patent No. 5,584,885, issued December 17, 1996;
7. Hadden, U.S. Patent No. 5,632,983, issued May 27, 1997;
8. Rise, U.S. Patent No. 5,643,207, issued July 1, 1997;
9. Elsberry et al., U.S. Patent No. 5,711,316, issued January 27, 1998;
10. Kmiec, U.S. Patent No. 5,731,181, issued March 24, 1998;
11. Elsberry, U.S. Patent No. 5,735,814, issued April 7, 1998;
12. Medencia et al., U.S. Patent No. 5,736,129, issued April 7, 1998;
13. Otto, U.S. Patent No. 5,769,823, issued June 23, 1998;
14. Kmiec, U.S. Patent No. 5,795,972, issued August 18, 1998;
15. Elsberry et al., U.S. Patent No. 5,814,014, issued September 29, 1998;
16. Elsberry et al., U.S. Patent No. 5,832,932, issued November 10, 1998;
17. Weiss et al., U.S. Patent No. 5,980,885, issued November 9, 1999;
18. Kumar et al. U.S. Patent No. 6,004,804, issued December 21, 1999;
19. Kmiec et al., U.S. Patent No. 6,010,907, issued January 4, 2000;
20. Elsberry, U.S. Patent No. 6,042,579, issued March 28, 2000;
21. Elsberry, U.S. Patent No. 6,093,180, issued July 25, 2000;
22. Soykan et al., U.S. Patent No. 6,151,525 issued November 21, 2000; and
23. Soykan et al., U.S. Patent No. 6,206,914 issued March 27, 2001.

### Foreign Patents

1. Elsberry et al., PCT Publication No. WO 97/40874, issued November 6, 1997;
2. Stokes et al., PCT Publication No. WO 98/02040, issued January 22, 1998;
3. Stokes et al., PCT Publication No. WO 98/02150, issued January 22, 1998;
4. Haynes et al., PCT Publication No. WO 98/15615, issued April 16, 1998;
5. Elsberry et al., PCT Publication No. WO 98/48723, issued November 5, 1998.

### Other References

BANNER & WITCOFF, LTD.  
10 South Wacker Drive  
Suite 3000  
Chicago, Illinois 60606  
Telephone: (312) 715-1000  
Facsimile: (312) 715-1234

- 1 Metzler, M., Helgason, C., Dragatsis, I., Zhang, T., Gan, L., Pineult, N., Zeitlin, S., Humphries, R., and Hayden, M., "Huntington is required for normal hematopoiesis," *Hum. Mol. Genet.* 9: 387-94 (2000)
2. Kren, B., Cole-Strauss, A., Kmiec, E., and Steer, C., "Targeted nucleotide exchange in the alkaline phosphatase gene of HuH-7 cells mediated by a chimeric RNA/DNA oligonucleotide," *Hepatology* 25: 1462-8 (1997)
3. Kren, B., Bandyopadhyay, P., and Steer, C., "In vivo site-directed mutagenesis of the factor IX gene by chimeric RNA/DNA oligonucleotides," *Nature Medicine* 4: 285-90 (1998)
4. Kren, B., Parashar, B., Bandyopadhyay, P., Chowdhury, N., Chowdhury, J., and Steer, C., "Correction of the UDP-glucuronosyltransferase gene defect in the Gunn rat model of Crigler-Najjar syndrome type I with a chimeric oligonucleotide," *Proc. Natl. Acad. Sci. USA* 96: 10349-54 (1999)
5. Bandyopadhyay, P., Ma, X., Linehan-Stieers, C., Kren, B., and Steer, C., "Nucleotide exchange in genomic DNA of rat hepatocytes using RNA/DNA oligonucleotides- Targeted delivery of liposomes and polyethylenimine to the asialoglycoprotein receptor," *J. Biol. Chem.* 274: 10163-72 (1999)
6. Havre, P. and Kmiec, E. (1998) RecA-mediated joint molecule formation between O-methylated RNA/DNA hairpins and single-stranded targets. *Mol Gen Genet* 258 (6): 580-586
7. Gamper, H.J., Cole-Strauss, A., Metz, R., Parekh, H., Kumar, R. and Kmiec, E. (2000) A plausible mechanism for gene correction by chimeric oligonucleotides. *Biochemistry* 39 (19): 5808-5816
8. Cole-Strauss, A., Gamper, H., Holloman, W., Munoz, M., Cheng, N. and Kmiec, E. (1999) Targeted gene repair directed by the chimeric RNA/DNA oligonucleotide in a mammalian cell-free extract. *Nucleic Acids Research* 27 (5): 1323-1330
9. Klement, I., Skinner, P., Kaytor, M., Yi, H., Hersch, S., Clark, H., Zoghbi, H. and Orr, H. (1998) Ataxin-1 Nuclear Localization and Aggregation: Role in Polyglutamine-Induced Disease in SCA1 Transgenic Mice, *Cell*, Vol. 95, pg. 41-53, 10/2/98.

10. Ellerby, L., Andrusiak, R., Wellington, C., Hackam, A., Propp, S., Wood, J., Sharp, A., Margolis, R., Ross, C., Salvesen, G., Hayden, M. and Bredesen, D. (1999) Cleavage of atrophin-1 at caspase site aspartic acid 109 modulates cytotoxicity. *J Biol Chem* 274 (13): 8730-8736
11. Faber, P., Alter, J., MacDonald, M. and Hart, A. (1999) Polyglutamine-mediated dysfunction and apoptotic death of a *caenorhabditis elegans* sensory neuron. *Proc Natl Acad Sci USA* 96 (1): 179-184
12. Prospects of Chimeric RNA-DNA Oligonucleotides in Gene Therapy, Xue-Song Wu, De-Pei Liu Chih-Chuan Liang, National Laboratory of Medical Molecular Biology, Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, PRC; *Journal of Biomedical Science*, 2001 8:439-445.
13. Targeted Gene Repair and Its Application to Neurodegenerative Disorders, Hetal Parekh-Olmedo, et al., Department of Biological Sciences Delaware Biotechnology Institute University of Delaware Newark, Department of Neurology Massachusetts General Hospital Harvard Medical School Boxton MA, *Neuron*, Vol. 33, 495-498, February 14, 2002.
14. Recombinant Proteins for Neurodegenerative Diseases: The Delivery Issue, Patrick Aebsicher et al., *Trends in Nerosciences* Vol. 24, No. 9 September 2001.
15. Whittemore et al, Gene Therapy and the Use of Stem Cells for Central Nervous System Regeneration, *Advances in Neurology* Vol 72, pp. 113-119 (1997).
16. Will, et al. "Regeneration in Brain and Spinal Cord", Cellular and Molecular Basis of Regeneration From Invertebrates to Humans", pp. 379-397, Willey & Sons (1998).
17. Stitchel-Gunkel, "The Role of the Microenvironment in Axonal Regeneration," *Advances in Anatomy, Embryology and Cell Biology* 137 (1997).
18. Gorio, Neuroregeneration, deVellis, "Supporting Cells Central and Peripheral", Chapter 4, pp. 61-62 (1992).
19. Berry and Logan, CNS INJURIES: Cellular Responses and Pharmacological Strategies, Chapter 9, pp. 169-189 (1998).

20. Seil, M.D., "Neuronal Regeneration, Reorganization, and Repair," Advances in Neurology, Vol. 72, pp. 121-123 (1997).

Respectfully submitted,

BANNER & WITCOFF, LTD

Dated: October 27, 2003

By:

  
\_\_\_\_\_  
Scott A. Burow  
Reg. No. 42,373

BANNER & WITCOFF, LTD.  
10 South Wacker Drive  
Suite 3000  
Chicago, Illinois 60606  
Telephone: (312) 715-1000  
Facsimile: (312) 715-1234



RECEIVED

NOV 03 2003

**CERTIFICATE OF MAILING**  
**(PATENT APPLICATION)**

Express Mail No. EL941345632US

TECHNOLOGY CENTER R3700

Deposited: October 27, 2003

I hereby certify that the attached correspondence, identified below, is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

By: 

Application of: Hartlaub

Application No.: 10/005,789

Filing Date: November 8, 2001

Title: Infusion System for Creating Microenvironments in a Living Body

Transmitted herewith are the following documents:

- Fee Transmittal Form (1 page) in duplicate
- Transmittal Form (1 page) in duplicate
- Information Disclosure Statement (5 pages)
- PTO SB/08A (2 pages) with cited references attached
- Return Postcard

Attorney Case No.: 11738.00038

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

OCT 27 2003

TRANSMITTAL  
FORM

(to be used for all correspondence after initial filing)

Application Number

10/005,789

Filing Date

November 8, 2001

First Named Inventor

Hartlaub

Art Unit

3763

Examiner Name

Kathryn L. Thompson

Total Number of Pages in This Submission

Attorney Docket Number

11738.00038

RECEIVED  
NOV 03 2003  
TECHNOLOGY CENTER R3700

## ENCLOSURES (check all that apply)

 Fee Transmittal Form Fee Attached Amendment / Response After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 Assignment Papers  
(for an Application) Drawing(s) Licensing-related Papers Petition Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Address Terminal Disclaimer Request for Refund CD, Number of CD(s) \_\_\_\_\_ After Allowance Communication to Group Appeal Communication to Board of Appeals and Interferences Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) Proprietary Information Status Letter Other Enclosure(s)  
(please identify below):

PTO SB/08A with cited references attached.

Remarks

Being filed via Express Mail No.:EL941345632US

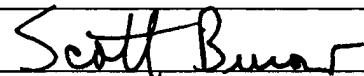
The Commissioner is hereby authorized to charge any deficiencies in payment or credit any overpayment to our Deposit Account 19-0733.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm  
or  
Individual name

Scott A. Burow

Signature



Date

October 27, 2003

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name

Signature

Date

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**FEES TRANSMITTAL  
for FY 2004**

OCT 27 2003  
Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

<b>TOTAL AMOUNT OF PAYMENT</b>	<b>(\$)</b> 180
--------------------------------	-----------------

**RECEIVED** NOV 03 2003  
TECHNOLOGY CENTER AS/700

METHOD OF PAYMENT (check all that apply)						FEE CALCULATION (continued)							
<input type="checkbox"/> Check <input type="checkbox"/> Credit card <input type="checkbox"/> Money <input type="checkbox"/> Other <input type="checkbox"/> None <input checked="" type="checkbox"/> Deposit Account						3. ADDITIONAL FEES							
Deposit Account Number	19-0733					Large Entity	Small Entity						
Deposit Account Name	Banner & Witcoff, LTD.												
The Director is authorized to: (check all that apply)													
<input checked="" type="checkbox"/> Charge fee(s) indicated below <input checked="" type="checkbox"/> Credit any overpayments <input type="checkbox"/> Charge any additional fee(s) during the pendency of this application <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.													
FEE CALCULATION													
1. BASIC FILING FEE													
Large Entity	Small Entity					Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description		Fee Paid	
1001	770	2001	385	Utility filing fee				1051	130	2051	65	SurchARGE - late filing fee or oath	
1002	340	2002	170	Design filing fee				1052	50	2052	25	SurchARGE - late provisional filing fee or cover sheet.	
1003	530	2003	265	Plant filing fee				1053	130	1053	130	Non-English specification	
1004	770	2004	385	Reissue filing fee				1812	2,520	1812	2,520	For filing a request for reexamination	
1005	160	2005	80	Provisional filing fee				1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
SUBTOTAL (1)				(\$)				1251	110	2251	55	Requesting publication of SIR after Examiner action	
				0				1252	420	2252	210	Extension for reply within first month	
								1253	950	2253	475	Extension for reply within second month	
								1254	1,480	2254	740	Extension for reply within third month	
								1255	2,010	2255	1,005	Extension for reply within fourth month	
								1401	330	2401	165	Notice of Appeal	
								1402	330	2402	165	Filing a brief in support of an appeal	
								1403	290	2403	145	Request for oral hearing	
								1451	1,510	1451	1,510	Petition to institute a public use proceeding	
								1452	110	2452	55	Petition to revive - unavoidable	
								1453	1,330	2453	665	Petition to revive - unintentional	
								1501	1,330	2501	665	Utility issue fee (or reissue)	
								1502	480	2502	240	Design issue fee	
								1503	640	2503	320	Plant issue fee	
								1460	130	1460	130	Petitions to the Commissioner	
								1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
								1806	180	1806	180	Submission of Information Disclosure Stmt	180
								8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
								1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
								1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
								1801	770	2801	385	Request for Continued Examination (RCE)	
								1802	900	1802	900	Request for expedited examination of a design application	
Other fee (specify) _____													
*Reduced by Basic Filing Fee Paid													
SUBTOTAL (3) (\$)													

\*or number previously paid, if greater; For Reissues, see above

SUBMITTED BY						Complete (if applicable)	
Name (Print/Type)	Scott A. Burow	Registration No. (Attorney/Agent)	42,373	Telephone	312-463-5000		
Signature	<i>Scott A. Burow</i>					Date	October 27, 2003

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.